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UNITED STATES DEPARTMENT OF COMMERCE
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#39

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,912,155 was filed on March 14, 1997, under 35 U.S.C. § 156. U.S. Patent No. 4,912,155 issued on March 27, 1990 from an application that was filed on February 27, 1987. Accordingly, the original expiration date of the patent is March 27, 2007.

The assistance of your Office is requested in confirming that the product identified in the application, 2,2'-ethylidenebis(4,6-di-tertbutylphenyl)fluorophosphonite, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use under the provisions of the provisions of law under which regulatory review occurred and that the application for patent term extension was filed within the sixty-day period after the product was given permission for commercial marketing or use. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Telephone inquiries regarding this communication should be directed to the undersigned at (703) 306-3159.

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Teresa Stanek Rea
Burns, Doane, Swecker & Mathis, LLP
PO Box 1404
Alexandria, VA 22313-1404

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